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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/816,900  | 04/05/2004  | Eckard Weber         | 2009.0010006/RWE/RAS | 2634             |
| 26111   | 7590        | 09/25/2006           | EXAMINER             |                  |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC<br>1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |             |                      | WINSTON, RANDALL O   |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 1655                 |                  |

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                 |                 |              |              |
|-----------------|-----------------|--------------|--------------|
| Application No. | 10/816,900      | Applicant(s) | WEBER ET AL. |
| Examiner        | Randall Winston | Art Unit     | 1655         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 26 June 2006.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 33-44 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 33-44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 0406.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Acknowledgment is made of receipt and entry of the amendment filed on 06/26/2006.

This action is made non-final due to a new ground of rejection.

Applicant's arguments have overcome examiner's priority rejection, double patent rejection, 35 U.S.C. 102(b) rejection and 35 U.S.C. 103(a) rejection in his non-final office action of 03/28/2006.

Claims 33-44 will be examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-41 are rendered vague and indefinite because applicant claims phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist within claim 33. Phentolamine mesylate is not another alpha adrenergic receptor antagonist as claimed in claims 40 and 41. It is suggest to applicant to delete the term "phentolamine mesylate" within the above claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-36 and 38-41 are rejected under 35 USC 102(e) as being anticipated by Scott (US 6,291,528).

Applicant claims a composition comprising between about 0.0018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier.

Scott anticipates the claimed invention (see, e.g. column 12 lines 33-38 and column 12 lines 39-42) because Scott teaches a composition comprising .25mg phentolamine mesylate and a pharmaceutically acceptable carrier and the claimed application. Therefore, the reference is deemed to anticipate the claimed invention.

Claims 33-35 and 40-41 are rejected under 35 USC 102(b) as being anticipated by Helmy (US 5,370,613).

Helmy anticipates the claimed invention (see, e.g. column 4 lines 49-55) because Helmy teaches a composition comprising .25mg phentolamine mesylate and a pharmaceutically acceptable carrier and the claimed application (i.e. by injection). Therefore, the reference is deemed to anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-44 are rejected under 35 US 103(a) as being unpatentable over Scott.

Applicant claims a composition and/or solution comprising between .00018 mg and about 0.45 mg phentolamine mesylate or a molar equivalent of another alpha adrenergic receptor antagonist and a pharmaceutically acceptable carrier present in a container that fits into a standard dental local anesthetic syringe for administration to a subject.

The primary reference is relied upon for the reasons discussed above. Scott does not expressly teach the composition is a solution is used to impregnate and the unit dosage of the solution is present in a container that fits into a standard dental local anesthetic syringe. However, based upon the overall beneficial teachings provided by Scott, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one type of administration for another, the solution is used to

impregnant and the form of the solution being placed in a container first than into a syringe), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 33-44 are rejected under 35 US 103(a) as being unpatentable over Helmy.

The primary reference is relied upon for the reasons discussed above. Helmy does not expressly teach the composition is a solution is used to impregnate, all the different types of administration and the unit dosage of the solution is present in a container that fits into a standard dental local anesthetic syringe. However, based upon the overall beneficial teachings provided by Helmy, the result-effective adjustment of conventional working conditions therein (e.g., the substitution of one type of administration for another, the solution is used to impregnate and the form of the solution being placed in a container first than into a syringe), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CHRISTOPHER R. TATE  
PRIMARY EXAMINER